
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

<p>BUZZIE SMITH, individually and on behalf of the Heirs and Estate of Charles A. Smith, Deceased,</p> <p style="text-align: center;">Plaintiff,</p> <p>v.</p> <p>TERUMO CARDIOVASCULAR SYSTEMS CORPORATION; IHC HEALTH SERVICES, INC.; INTERMOUNTAIN MEDICAL CENTER; INTERMOUNTAIN HEALTH CARE, INC.,</p> <p style="text-align: center;">Defendants.</p>	<p>MEMORANDUM DECISION AND ORDER GRANTING TERUMO CARDIOVASCULAR'S [152] MOTION TO EXCLUDE ALFRED STAMMERS</p> <p>Case No. 2:12-cv-00998-DN</p> <p>District Judge David Nuffer</p>
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The decedent Charles A. Smith (“Mr. Smith”), represented in this litigation by Buzzie Smith (“Mrs. Smith”), underwent surgery on his heart in September 2010. There were problems during the surgery. Eleven months later, Mr. Smith passed away. Mrs. Smith brings this action against the hospital and a manufacturer of a device used during the surgery.¹ To establish certain elements of her product liability claims against the device manufacturer, Mrs. Smith offers Alfred Stammers’s (“Mr. Stammers”) expert opinion and testimony. Defendant Terumo (“Terumo”) moves (“Motion”) to exclude Mr. Stammers’s opinion and testimony.² Mrs. Smith opposes the Motion (“Opposition”).³ Terumo replies in support of the Motion.⁴ As set forth

¹ Amended Complaint, [docket no. 17](#), filed October 7, 2013.

² Terumo Cardiovascular Systems Corporation’s Motion to Exclude Alfred Stammers (“Motion”), [docket no. 152](#), filed May 12, 2017.

³ Plaintiff’s Opposition to Terumo Cardiovascular System Corporation’s Motion to Exclude Alfred Stammers (“Opposition”), docket no 171, filed June 2, 2017.

⁴ Reply Memorandum in Support of Terumo Cardiovascular Systems Corporation’s Motion to Exclude Alfred Stammers (“Reply”), [docket no. 192](#), filed June 20, 2017.

below, Mr. Stammers is not qualified to offer an opinion on an alleged defect in the device used during the surgery and the methodology he uses to formulate that opinion is not reliable. The Motion is GRANTED.

Contents

Background	2
Discussion	4
1. Mr. Stammers lacks the necessary qualifications to opine on an alleged defect in the System 1	6
2. Even if Mr. Stammers is qualified to opine on a defect in the System 1, his opinion is not reliable.....	9
Order	11

BACKGROUND⁵

On September 13, 2010, Mr. Smith underwent heart valve replacement surgery (“September 2010 surgery”).⁶ As part of the surgery, a Terumo Advanced Perfusion System 1 heart/lung bypass machine (“System 1”) was used.⁷ The System 1 was to provide for the circulation of blood and oxygen through Mr. Smith’s body while surgery was being performed on his heart valve.⁸ At some point, the System 1 stopped working for 10–11 minutes.⁹ Eleven months later, on August 6, 2011, Mr. Smith passed away from a myocardial infarction, (*i.e.*, heart attack).¹⁰

⁵ As specified in the other decisions regarding motions to limit and exclude in this case, the undisputed material facts will be determined in the rulings on the motions for summary judgment. The facts described below are provided only for context and are taken as alleged in the Complaint.

⁶ Complaint ¶ 11.

⁷ *Id.* ¶ 12.

⁸ *Id.* ¶ 13.

⁹ *Id.* ¶¶ 15–17; although the Complaint fails to specify how many minutes the bypass machine was not working, the parties seem to agree on between 10 and 11 minutes. *See Motion at 4.*

¹⁰ *Id.*

Mrs. Smith hired Alfred Stammers, a licensed perfusionist, to offer opinions regarding the perfusion care provided to Mr. Smith during the September 2010 surgery. Included in Mr. Stammers's opinions is the following:

The cardiopulmonary bypass machine manufacturer (Terumo Cardiovascular Systems Corporation, from Japan with its main United States office in Ann Arbor, MI) provided its users with Air Bubble Detection Systems [ABD]¹¹ which created safety issues for patients, and which could have caused problems with allowing the operators of this Advanced Perfusion System 1 to establish forward arterial flow after the ABD detected an event. Safety alerts were issued by Terumo Cardiovascular for the Advanced Perfusion System 1 machine noting that inadvertent shut down of the cardiopulmonary bypass machine could occur related to issues concerning the Air Bubble Detection System, which resulted in an Urgent Medical Device Recall that occurred on June 18, 2012 (after the Smith surgery). [See also the Urgent Field Safety Notice FSN109 2011-03.] Absent evidence that Terumo had modified its ABD, then these problems existed at the time of the Smith surgery [and the recall states that “prior corrective actions on the sensor (from 2007 and 2010) did not fully eliminate the possibility for malfunction”]¹². Upon review of the Advanced Perfusion System 1 Report Log from the Smith surgery, it is evident that the centrifugal pump went into the ‘Coast’ mode as a response to an over-pressurization alarm that occurred.¹³

“As evidenced by the safety alerts and recall notices,” according to Mr. Stammers, this issue with the Air Bubble Detection system is a defective condition and “could render this cardiopulmonary bypass machine unreasonably dangerous in its operation . . . and dangerous to the safety of patients, and could cause the injuries to a patient, including Charles Smith, due by an inadequate forward flow during perfusion.”¹⁴ Because “no evidence has been presented that this Terumo Advanced Perfusion System 1 machine used in the [September 2010 surgery], which was sold by Terumo and installed by Terumo at Intermountain Medical Center in 2007, was altered by Intermountain Medical Center,” Mr. Stammers ultimately concludes that “this

¹¹ This bracketed text is supplied in this order.

¹² This bracketed text and the brackets are in Stammers’s report.

¹³ Plaintiff’s Rule 26(a)(2)(B) Retained Expert Disclosure Statement, Exhibit 1, Report of Opinions Rendered by Alfred H. Stammers (“Stammers Report”) at 4, [docket no. 143-1](#), filed February 8, 2017.

¹⁴ *Id.* at 5.

defective condition was present when this cardiopulmonary bypass machine was sold by Terumo to [Intermountain Medical Center].”¹⁵

DISCUSSION

Terumo does not dispute that Mr. Stammers is qualified to opine on the standard of care applicable to perfusionists and facilities where perfusion services are offered.¹⁶ However, Terumo argues that Mr. Stammers’s opinions and testimony regarding the presence of an alleged defect in the System 1 should be excluded for two reasons. First, Terumo argues that that Mr. Stammers is not qualified to “testify about a potential defect in the System 1 that may (or may not) have exhibited itself during the [September 2010 surgery]” because he “has no experience in product design, development, or manufacture.”¹⁷ And second, Terumo argues that because “Mr. Stammers has engaged in nothing more than a review of Terumo safety notices and deposition testimony to conclude it is possible the System 1 malfunctioned[,]” Mr. Stammers has not “engage[d] in any analysis, let alone a reliable analysis to conclude that it was possible that the System 1 malfunctioned.”¹⁸

Federal Rule of Evidence 702 establishes the standard for the admissibility of expert testimony.

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.¹⁹

¹⁵ *Id.*

¹⁶ Motion at 4.

¹⁷ *Id.* at 2.

¹⁸ *Id.* at 13.

¹⁹ Fed. R. Evid. 702.

“Under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.”²⁰ The inquiry of scientific reliability is flexible and focuses on principles and methodology.²¹ The Supreme Court has offered several nonexhaustive factors that a court may rely on for determining reliability such as, whether the testimony can be tested, has been peer reviewed, has a known or potential rate of error, and has attracted acceptance in the relevant scientific community.²²

District courts serve as the gatekeepers of expert evidence, and must therefore decide which experts may testify and present evidence before the jury.²³ Courts are given “broad latitude” in deciding “how to determine reliability” and in making the “ultimate reliability determination.”²⁴ The Federal Rules of Evidence, however, generally favor the admissibility of expert testimony.²⁵ Excluding expert testimony is the exception rather than the rule, and often times the appropriate means of attacking shaky but admissible evidence is through vigorous cross-examination, and the presentation of contrary evidence.²⁶ “[T]he Federal Rules of Evidence favor the admissibility of expert testimony, and [courts’] role as gatekeeper is not intended to serve as a replacement for the adversary system.”²⁷

²⁰ *Daubert v. Merrell Dow Pharmas., Inc.*, 509 U.S. 579, 589 (1993).

²¹ See *Id.* at 595.

²² See *Id.*

²³ See *Id.*

²⁴ *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 142 (1999), (citing *General Electric Co. v. Joiner*, 522 U.S. 135 (1997)).

²⁵ See *Daubert*, 509 U.S. at 588.

²⁶ See Fed. R. Evid. 702 Advisory Notes.

²⁷ *THOIP v. Walt Disney Co.*, 690 F. Supp. 2d 218, 230 (S.D.N.Y. 2010).

The inquiry into whether an expert's testimony is reliable is not whether the expert has a general expertise in the relevant field, but whether the expert has sufficient specialized knowledge to assist jurors in deciding the particular issues before the court.²⁸

Expert testimony is subject to Federal Rule of Evidence 403. "The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."²⁹

In determining whether expert testimony is admissible the first step is to determine whether the expert is qualified, and then if the expert is qualified determine whether the expert's opinion is reliable by assessing the underlying reasoning and methodology.³⁰ If the expert is qualified and the opinion reliable, the subject of the opinion must be relevant; i.e. the opinion must "help the trier of fact to understand the evidence or to determine a fact in issue."³¹ "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful."³²

1. Mr. Stammers lacks the necessary qualifications to opine on an alleged defect in the System 1

In Mr. Stammers's opinion, the air bubble detection system on the System 1 generated a false alarm during the September 2010 surgery.³³ This false alarm, according to Mr. Stammers, is a defective condition that renders the System 1 unreasonably dangerous.³⁴ Despite

²⁸ *Kumho*, 526 U.S. at 156.

²⁹ Fed. R. Evid. 403.

³⁰ *U.S. v. Nacchio*, 555 F.3d 1234, 1241 (10th Cir. 2009).

³¹ Fed. R. Evid. 702 (emphasis added).

³² *Daubert*, 509 U.S. at 591.

³³ Stammers Report at 4; Exhibit 2, Deposition of Alfred H. Stammers ("Stammers Deposition") at 98: 13–19, docket no. 152, filed May 12, 2017.

³⁴ Stammers Report at 5.

acknowledging that Mr. Stammers is an expert in perfusion and possesses the requisite knowledge to *operate* the System I, Terumo argues that “expertise in proper perfusion techniques is not sufficient to analyze the design and technical functionality of a heart bypass machine.”³⁵ Absent the appropriate qualifications based on necessary engineering or mechanical knowledge, Terumo maintains that Mr. Stammers cannot “say, with any degree of expertise and reliability, that the System 1 malfunctioned or was defective.”³⁶

To qualify as an expert under Federal Rule of Evidence 702, the expert must have “such skill, experience or knowledge in that particular field as to make it appear that his opinion would rest on substantial foundation and would tend to aid the trier of fact in his search for truth.”³⁷ “[A]s long as an expert stays within the reasonable confines of his subject area . . . a lack of specialization does not affect the admissibility of [the expert] opinion, but only its weight.”³⁸ “The dispositive question” is whether the opinion that the expert offers can be considered “within the reasonable confines of [the expert’s] subject area.”³⁹

Mr. Stammers’s own admissions show that his ultimate opinion that the System 1 contained a defect is outside the reasonable confines of his expertise as a perfusionist. Immediately following Mr. Stammers’s explanation in his deposition of his current status as a Certified Clinical Perfusionist, Mr. Stammers admits that he is not an engineer and does not intend to offer any sort of engineering or manufacturing opinion, specifically as to the design of medical devices:

³⁵ Motion at 12.

³⁶ *Id.* at 3.

³⁷ *LifeWise Master Funding v. Telebank*, 374 F.3d 917 (10th Cir. 2004) (internal quotation marks and citation omitted).

³⁸ *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001) (internal citation omitted).

³⁹ *Id.*

Q: My understanding, Mr. Stammers, that you don't consider yourself an engineer?

A: That is correct.

Q: And you don't intend to express any opinions that would be on engineering?

A: No, sir.

Q: And would that include opinions relating to design engineering as it relates to medical devices?

A: That is correct.⁴⁰

The issuance of a field safety notice by Terumo is key to Mr. Stammers's opinion that alarm generated System 1's air bubble detection system was a false alarm and therefore a defective condition:

Q: . . . Do you have any reason to believe that in the course of the Smith procedure there was a false alarm related to --- generated by the air bubble detection system?

A: It could have happened, yes.

Q: And what's that based on?

A: It's based upon the safety notice that was sent by Terumo titled Urgent Medical Device Recall.⁴¹

However, when Mr. Stammers is asked about his understanding of the content of the Terumo field safety notice, he admits that he does not have the specialized engineering expertise that would allow him to offer an opinion on *why* the issues described in the notice might occur:

Q: And I gather that you don't have any engineering understanding of what accounts for this particular issue that's described in this urgent field safety notice from a mechanical engineering point of view?

A: No, sir.⁴²

This admitted lack of mechanical engineering or design expertise erodes the foundation of his opinion regarding an alleged defect in the System 1. If Mr. Stammers cannot understand or provide an explanation for the issue that leads him to the conclusion that the System 1 contained a defect, he cannot provide testimony that aids the jury in their role as fact finders. A review of

⁴⁰ Stammers Deposition at 80:17–25.

⁴¹ *Id.* at 98:15–22.

⁴² *Id.* at 119:06–10.

Mr. Stammers's curriculum vita⁴³ confirms that Mr. Stammers is a well-qualified perfusionist. Terumo even concedes that Mr. Stammers may testify to the standard of care applicable to other perfusionists.⁴⁴ But he is not qualified to testify as to a potential defect in the System 1. It is appropriate to exclude him from testifying on this issue.

2. Even if Mr. Stammers is qualified to opine on a defect in the System 1, his opinion is not reliable.

Terumo contends that even if Mr. Stammers is qualified to opine on a potential defect in the System 1, the process by which he arrived at that opinion is unreliable. To form his opinions, Mr. Stammers reviewed depositions, reports, systems logs, and medical records, making “reasonable extrapolations therefrom” based upon his education, training, experience and knowledge regarding perfusion.⁴⁵ Terumo argues that Mr. Stammers’s reliance on the depositions of others and the failure to conduct any sort of testing cannot be considered to be a reliable analysis supporting the conclusion that the System 1 suffers from a defect.⁴⁶

“[A] district court may properly exclude [expert] testimony” when the opinion evidence “is connected to existing data only by the *ipse dixit* of the expert” such that “there is simply too great an analytical gap between the data and the opinion offered.”⁴⁷ This analytical gap exists when an expert report fails to include the expert’s attempts to test his theory, as a “key question to be answered in determining whether a theory or technique is scientific knowledge that will

⁴³ Plaintiff’s Rule 26(a)(2)(B) Retained Expert Disclosure Statement, Exhibit 2, Report of Opinions Rendered by Alfred H. Stammers (“Stammers Report”) at 4, [docket no. 143-2](#), filed February 8, 2017.

⁴⁴ Motion at 2.

⁴⁵ Stammers Report at 1, 6–9.

⁴⁶ Reply at 4–5.

⁴⁷ *Heer v. Costco Wholesale Corp.*, 589 Fed. App’x 854, 861 (10th Cir. 2014) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)) See *Heer* 589 Fed. App’x at 861 at n. 4 (“*Ipse dixit*” is Latin for ‘He, himself, said it,’ and is used to identify an unsupported statement that rests solely on the authority of the person who makes it.” (citing *Black’s Law Dictionary* 905 (9th ed.2009))).

assist the trier of fact will be whether it can be (and has been) tested.”⁴⁸ The Tenth Circuit has held that, although testing is not always required to satisfy the reliability threshold of Rule 702, it is particularly important where the basis for the expert opinion is subject to debate.⁴⁹

Mr. Stammers’s report and his proposed testimony suffer from this sort of analytical gap for the aforementioned reasons. His report clearly states that he formulated his opinions based on a review of the depositions, reports, system logs, and medical records.⁵⁰ However, nothing in his report or deposition testimony indicates that, after consulting those materials and developing a theory that the System 1 might have a defect, he made any attempt to test that theory. Instead, after taking the field safety notice issued by Terumo into account, Mr. Stammers concludes that the System 1 issued a false alarm.⁵¹ And then he makes his ultimate conclusion that the System 1 contained a defect.⁵² His analytical leap is debatable. Without testing, his conclusion is only a theory with inadequate support.

Because Mr. Stammers relies exclusively on the accounts and reports of others, rather than a rigorous scientific and analytical process of his own to arrive at a reliable opinion, it is unsurprising that his deposition would include the admission that he cannot explain why the System 1 used in the September 2010 surgery performed in the manner that it did:

Q. But as you said, you can’t explain what that alleged malfunction was or how it occurred?

A. No, I don’t believe anybody has been able to explain it in all of the due diligence that has gone into trying to understand exactly what occurred in this case.⁵³

⁴⁸ *Daubert*, 509 U.S. at 593

⁴⁹ *Heer*, 589 F. App’x at 862 (citing *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1235–36 (10th Cir.2004)).

⁵⁰ Stammers Report at 6–9.

⁵¹ Stammers Deposition at 98:15–22.

⁵² Stammers Report at 4.

⁵³ Stammers Deposition at 111:2–7.

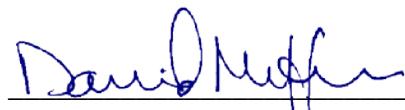
Mr. Stammers cannot offer an expert opinion regarding an alleged product defect, when he has not attempted to test his theory and cannot adequately explain the alleged defect, and, in particular, how the type of machine in question behaved as a result of that defect. The analytical gap between the data and his opinion, without supporting testing, is too great for Mr. Stammers's opinion to be considered reliable under Rule 702. Therefore exclusion is appropriate.

ORDER

IT IS HEREBY ORDERED that Terumo Cardiovascular Systems Corporation's Motion to Exclude Alfred Stammers⁵⁴ is GRANTED.

Signed August 7, 2017.

BY THE COURT



District Judge David Nuffer

⁵⁴ Terumo Cardiovascular Systems Corporation's Motion to Exclude Alfred Stammers ("Motion"), [docket no. 152](#), filed May 12, 2017.